IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TWINSTRAND BIOSCIENCES, INC. & UNIVERSITY OF WASHINGTON, Plaintiffs and Counterclaim Defendants, v. GUARDANT HEALTH, INC., Defendant and Counterclaim Plaintiff.	C.A. No. 21-1126-GBW-SRF [redacted] PUBLIC VERSION FILED OCTOBER 21, 2022

SEALED RESPONSIVE LETTER FROM JEFF CASTELLANO TO JUDGE FALLON

Dear Judge Fallon:

Guardant is pleased to report that the parties have partially resolved this dispute by agreement. Specifically, the parties have reached an agreement that moots the portion of Plaintiffs' motion to compel as it relates to the Guardant Companion and Guardant Explore services. The scope of the dispute is now limited to the remaining two services: Guardant Inform and Guardant Connect.

As explained in Guardant's opening letter brief, Plaintiffs' patents-in-suit are directed to methods of sequencing DNA. Plaintiffs have accused various Guardant products of performing the claimed methods (*e.g.*, the Guardant360 and GuardantOMNI). (D.I. 127, Ex. A). Plaintiffs have also alleged that the Guardant Inform and Guardant Connect *services* infringe because they "require data" generated by the test kits, despite the fact that Inform and Connect ***undisputedly do not perform the claimed methods***. Plaintiffs have never explained their theory of infringement with regard to Inform and Connect. Instead, they seek to shift the burden of proving infringement to Guardant, and to force invasive technical discovery on Guardant in the meantime. Plaintiffs' improper and overreaching motion should be denied.

A. Guardant Inform and Guardant Connect Are Not Properly Accused Products

As set forth in Guardant's opening letter brief, Plaintiffs have never provided a claim chart or other information showing how the Inform and Connect services allegedly perform the claimed sequencing methods. (D.I. 126 at 2-4). Plaintiffs' inability to support their position demonstrates that Inform and Connect were never properly accused and should be stricken. In other words, "the only accused products are the ones for which the plaintiff has done infringement contentions and complete claim charts." *Round Rock Rsch. LLC v. Lenovo Grp. Ltd.*, C.A. No. 11-1011-RGA, D.I. 86 (D.I. 126, Ex. P) (D. Del. Jun. 14, 2013) (rejecting plaintiff's request for "complete discovery responses" regarding non-charted products).

Plaintiffs state that their initial infringement contentions "accused Guardant of infringing the patents-in-suit by performing its Accused Services." (D.I. 127 at 1). But even a cursory examination of those contentions reveals that Plaintiffs simply designated Guardant's services as "accused" because they "***require data*** obtained by performing the Accused Products." *Id.* at Ex. A (emphasis added). Plaintiffs' initial claim charts did not even mention the Inform or Connect services, let alone make an attempt to perform an element-by-element infringement analysis. *See V-Formation, Inc. v. Benetton Group SpA*, 401 F.3d 1307, 1312 (Fed. Cir. 2005) ("Literal infringement requires that each and every limitation set forth in a claim appear in an accused product.").

In the months since Plaintiffs provided their contentions, they have never provided any semblance of support for their apparent position that the Inform and Connect service infringe the asserted claims. Guardant has repeatedly requested that Plaintiffs amend their contentions to provide claim charts for the accused Guardant services, including Inform and Connect, or withdraw them. (Ex. A at 1 ("the 'Accused Services' were not accused in Plaintiffs' complaint and do not perform any

genomic sequencing"); Ex. B at 3 (noting that the services "have … nothing to do with the claimed methods" and requesting that plaintiffs withdraw their contentions of infringement); Ex. C at 1 (requesting that Plaintiffs provide a "tenable basis for their infringement allegations as to the Accused Services" to justify additional discovery).[1]

Plaintiffs did amend their contentions, but rather than providing complete claim charts for the Inform or Connect, they included only a single passing reference to Inform and Connect in each chart, stating in a conclusory fashion that each service "uses the same sequencing methods that [Guardant] performs in at least one of the Accused Products." (D.I. 126, Ex. I at 9-11). But the cited documents do not support Plaintiffs' statement, nor do any of the dozens of other technical, marketing, and process documents Guardant has provided regarding Inform and Connect. (D.I. 126 at 3-4).

Plaintiffs' request for discovery on products for which it has not identified any basis for its allegation of infringement is inconsistent with the long line of cases in this District restricting discovery to properly accused products. For example, in *Honeywell*, Judge Jordan explained that patentees must have a demonstrated "basis" for alleging infringement before obtaining discovery on the products at issue. *Honeywell Int'l, Inc. v. Audiovox Commc's Corp.*, C.A. No. 04-1337-KAJ, 2005 U.S. Dist. LEXIS 41822, at *3 n.2 (D. Del. Oct. 7, 2005). He explained that it would be improper to shift this burden to the defendants:

> I agree with the defendants that now what you are doing is telling manufacturers, you know what? You got one or two things that are bad. We want to you do an analysis of everything you make and tell us whether you are guilty on those fronts, too; and that is not what the law requires, and it's not what I'm going to require them to do.

Id. Plaintiffs have established no such basis here, as set forth above and in Guardant's opening letter. *See also Invensas Corp. v. Renesas Elecs. Corp.*, 287 F.R.D. 273 (D. Del. 2012). Plaintiffs must articulate *with specificity* how the Inform and Connect services are relevant to existing claims of infringement, and thus how they are "reasonably similar" to the accused products in some way relevant to the asserted claims. *Id.* at 282. Even where some of the information needed to make out a claim of infringement is non-public, that cannot "shift the burden from Plaintiff to Defendant

[1] The statement by Guardant's counsel selectively quoted by Plaintiffs (D.I. 127 at 2) was yet another attempt to convey to Plaintiffs that the Inform and Connect services do not themselves perform sequencing, and that therefore the documents sought by Plaintiffs related to those services would be irrelevant to their claims of infringement. In fact, the very next sentence after the excerpt in Plaintiffs' letter states: "For that reason, any technical information regarding the underlying test kits and sequencing technology has already been produced in connection with the technical production related to the accused *products*." (D.I. 127 at Ex. F (emphasis added)). It is followed by a statement that the documents Guardant has already produced "definitively establish that there is no basis to allege that the Guardant Inform and Guardant Connect services perform the methods set forth in the asserted claims, and should be removed from plaintiffs' contentions." *Id.*

to be the party responsible for articulating why certain of those products do in fact infringe Plaintiff's patents." *Id.* at 286.

Here, the case for denying Plaintiffs' motion to compel is even stronger than in *Honeywell* and *Invensas*, because in those cases it was possible that the discovery would show that the products infringed, but here, the Inform and Connect services cannot infringe because they do not themselves perform sequencing methods, and Plaintiffs have never pointed to any information showing otherwise.[2]

And while the scope of discovery may be broad, it is limited to relevant information and in numerous other ways, and may be further limited by the Court. Fed. R. Civ. P. 26(b)(1), (c). Plaintiffs cannot show that the information sought regarding Inform and Connect is relevant to their assertions of infringement of the claimed sequencing methods.

B. Guardant Has Already Produced Documents on Inform and Connect

Guardant has produced hundreds of pages of documents pertaining to the Inform and Connect services. Contrary to Plaintiffs' suggestions at pages 2-3 of their letter, Guardant has provided and specifically identified for Plaintiffs documents that contain the listed information, including which products' data is relied upon by each service, how the services are marketed, who performs the services, and the design and functionality of the services. *E.g.*, Ex. D; Ex. E; Ex. F (including exemplary marketing documents, showing that Inform and Connect rely on data generated by Guardant360 test kits, and showing the schematic details of the Guardant Inform and Connect services, including the platform architecture for Inform). *See also* D.I. 126, Exs. L-N.

Guardant has gone above and beyond its obligations to provide technical, marketing, and process information related to the Inform and Connect services, where Plaintiffs have never provided any claim chart or otherwise explained the basis for its position that these services infringe the asserted sequencing method patents. Even if Plaintiffs had a colorable basis to allege that Connect and Inform perform the sequencing method set forth in the asserted claims, that information has never been provided to Guardant. Even now, when asking the Court to force Guardant to provide costly and burdensome discovery on Connect and Inform, it cannot muster any support for its position that Connect and Inform infringe.

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[2] Plaintiffs' citation to *Greatbatch* (D.I. 127 at 3) is unavailing because in this case Guardant has already produced documents showing the relationship (or lack thereof, more accurately) of the Inform and Connect services to the methods performed by the accused products. *See* Section B. Moreover, the patentee in *Greatbatch* had not refused for months to substantiate its claim of infringement despite receiving a host of documents related to the purportedly accused products. Here, there is very little to support the central tenet of Judge Burke's ruling in that case – the belief "that the plaintiff must have a good faith basis for whatever it is accusing." *Greatbatch Ltd. v. AVX Corp.*, 179 F. Supp. 3d 370, 374 (D. Del. 2016).

For the above reasons, Plaintiffs' motion to compel should be denied.

Respectfully,

/s/ Jeff Castellano

Jeff Castellano (No. 4837)

EXHIBIT A

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February 25, 2022
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Re: TwinStrand Biosciences, Inc. et al. v. Guardant Health, Inc., No. 21-cv-1126-LPS (D. Del.)

Dear Anna:

I write in response to your February 17, 2022 letter regarding the parties' February 4, 2022 meet and confer. As a preliminary matter, we disagree with some elements of your summary as outlined below. As we represented during the meet and confer, Guardant is working diligently to supplement its interrogatory responses. Discovery is ongoing, and Guardant is not required to submit complete interrogatory responses at this time.

I also note that during the parties' February 15, 2022 meet and confer, you stated that you would provide a letter articulating the basis for which Plaintiffs contend that the documents sought in Plaintiffs' Second Set of Requests for Production are relevant. Please let us know when you will have that letter drafted by so we can reach a timely resolution on those outstanding issues.

I. Guardant's general objections to certain defined terms are proper

a. General Objection No. 16: LUNAR-2

[redacted] Guardant has collected documents pertaining to the LUNAR-2. [redacted] Guardant will promptly supplement its production and interrogatory responses to include the LUNAR-2.

b. General Objection No. 17: "Accused Services"

As we stated during the meet and confer, the "Accused Services" were not accused in Plaintiffs' complaint and do not perform any genomic sequencing. That said, Guardant has agreed to, and has indeed produced, documents pertaining to the Accused Services (*see i.e.* GH00006952 - GH00006989). After reviewing those documents, if Plaintiffs can articulate a tenable basis for their infringement allegations against the "Accused Services," Guardant will revisit its objection.

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c. General Objection No. 18: "Digital Sequencing Technology"

As we represented during the meet and confer, we are working diligently with our client to identify any information that related to "Digital Sequencing Technology." [redacted] Further, we requested clarification from Plaintiffs as to their definition of the term, which is ambiguous, vague, and overbroad. To date, Plaintiffs have offered no clarification or concrete definition.

d. General Objection No. 19: "Error Correction Approaches For Next-Generation Sequencing"

As discussed during the meet and confer, [redacted] nor is it a term that is generally understood in the industry. The definition of the term provided in Plaintiff's discovery requests is unintelligibly broad and vague: "any solution, technique, technology, or method that, compared to a raw sequencing read for a given nucleic acid sequence, reduces the error rate, identifies a probable error, or identifies a probable mutation in any next-generation sequencing approach for sequencing polynucleotide molecules, and shall include, without limitation, error correction, error identification, error suppression, and variant identification solutions, techniques, technologies, and methods." As such, we requested that you provide clarification as to what you seek in response to requests and interrogatories directed to "Error Correction Approaches For Next-Generation Sequencing" which you have not done. If Plaintiffs' can provide a concrete definition of "Error Correction Approaches For Next-Generation Sequencing" or clarify what it is that they seek in response to requests and interrogatories directed to "Error Correction Approaches For Next-Generation Sequencing" Guardant will update its production and interrogatory responses. As currently defined, "Error Correction Approaches For Next-Generation Sequencing" is far too broad and vague for Guardant to identify responsive documents and provide interrogatory responses.

II. Guardant's Responses to Plaintiffs' First Set of Interrogatories

a. Interrogatory Nos. 9–13 and 15

Guardant repeatedly represented that it will supplement each of its interrogatory responses as it is able to. Now that discovery is underway, Guardant is able to supplement its responses to Interrogatories Nos. 9-13 and 15. Guardant will work diligently to supplement its responses by March 10, 2022, though it cannot guarantee that it will be able to do so by that date for all responses.

b. Interrogatory Nos. 4 and 7

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Guardant is unclear as to what specificity Plaintiffs seek in response to Interrogatory No. 7. Guardant's Accused Products share common technology and Stefanie Mortimer and Bill Getty are knowledgeable as to all Accused Products. Guardant will supplement its response to make this more apparent. Please let us know what specificity Plaintiffs seek with respect to Guardant's identification of Stefanie Mortimer and Bill Getty so that Guardant may assess whether it will be able to provide such specificity.

c. Interrogatory No. 6

Guardant is working diligently to identify information regarding its first awareness of each Asserted Patent. Guardant will supplement its response to Interrogatory No. 6 when it has done so.

d. Interrogatory No. 14

Guardant has confirmed that this was a typographical error and will supplement accordingly.

Best regards,

Monica De Lazzari

MID:

EXHIBIT B

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April 6, 2022

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Re: TwinStrand Biosciences, Inc. v. Guardant Health, Inc., C.A. No. 21-1126-VAC (D. Del.)

Dear Anna:

We are writing with regard to Plaintiffs' Initial Claim Charts on Infringement, served April 1, 2022.

We have reviewed the claim charts and the contentions contained therein, and have been unable to discern plaintiffs' positions regarding infringement beyond plaintiffs' apparent belief that essentially all of Guardant's products and services infringe every single claim of the asserted patents (108 claims in total). The charts disclose essentially no information beyond that broad general accusation.

As a result of plaintiffs' failure to provide adequate infringement contentions, Guardant's ability to develop claim construction positions, invalidity contentions, and non-infringement contentions, and more broadly its ability to develop a strategy for responding to plaintiffs' claims, has been and continues to be impeded. Plaintiffs' failure, if not immediately remedied, risks disruption of the Court-ordered schedule.

Addressing all of the failings in plaintiffs' charts would be an undertaking far out of proportion with the effort put into assembling the charts in the first place. Rather than identifying every single deficiency in plaintiffs' charts, we are providing in this letter a non-exhaustive and illustrative list of deficiencies.

We request that plaintiffs supplement their claim charts immediately to address the problems identified herein with the information currently in their possession, custody, or control. If plaintiffs do not immediately supplement, Guardant intends to move to strike or preclude any later-added theory or evidence that plaintiffs could have added in its initial contentions, and further reserves the right to strike the initial contentions themselves at least for the reasons below.

We are available to meet and confer. Please provide your availability to meet and confer on or before April 8, 2022.

Deficiencies

1. **Overly Broad List of "Accused Products"**

Plaintiffs' claim charts (including the cover pleading) appear to accuse the below products and services:

- Guardant's Guardant360 lab developed test
- Guardant360CDx
- GuardantOMNI
- Guardant Reveal
- Guardant LUNAR-2
- Guardant360 Response
- Guardant360 TissueNext
- Guardant Connect
- Guardant Inform
- Guardant Companion
- Guardant Explore

It appears that plaintiffs' accusation of infringement of all of the above products and services is based on what plaintiffs refer to as Guardant's [redacted] ('361 Chart at 1). Plaintiffs assert that [redacted] use its sequencing platform.

But plaintiffs acknowledge that a number of the Accused Products[1] do not themselves use the allegedly infringing sequencing technology. Plaintiffs state on page 2 of the '631 chart, for example, that Guardant Response, Guardant Connect, Guardant Inform, Guardant Companion, and Guardant Explore [redacted]

Plaintiffs make no attempt to provide a link between the asserted claims of the patents-in-suit and these five products and services, other than their assertions that these products and services appear to rely in some fashion on data produced by the allegedly infringing

[1] By using this term, Guardant does not concede that any of its products or services are properly accused.

products. Plaintiffs provide no claim charts for these products and services. In fact, plaintiffs appear to acknowledge that at least some of these products and services have essentially nothing to do with the claimed methods. [redacted][2]

In light of plaintiffs' failure to identify any basis for infringement of Guardant Response, Guardant Connect, Guardant Inform, Guardant Companion, and Guardant Explore, we request that plaintiffs immediately withdraw their claims of infringement with regard to those products and services. If plaintiffs do not, Guardant plans to move to strike these products from the case.

Please note that by identifying this deficiency, Guardant is not admitting that plaintiffs have properly or adequately accused any of the products or services identified in plaintiffs' initial claim charts.

2. Parroting and Failing to Address Claim Language

With respect to the vast majority of claim limitations addressed in plaintiffs' charts, plaintiffs simply re-state a portion of the relevant claim language and do not provide any additional explanation or indication as to how the Accused Products (including the 6 products identified in the charts and the 5 entirely uncharted products) practice the limitation.

Surprisingly, although the entirety of plaintiffs' analysis seems to be repeating claim language, plaintiffs fail to address large swaths of the claims altogether, including crucial limitations.

For example, plaintiffs' claim chart for claim 1 of the '699 Patent is reproduced below, with document citations removed. The yellow highlighting shows repeated claim language. The red highlighting shows claim language that plaintiffs failed to address altogether.

Claim Language	**Plaintiffs' Evidence of Infringement**
A method, comprising:	To the extent the preamble is considered limiting, Guardant's sequencing platform includes a method for next generation

[2] A reference to one of plaintiffs' charts should be understood to apply to the other charts as well.

	sequencing.
a) providing a population of circulating DNA molecules obtained from a bodily sample from a subject;	Guardant's sequencing platform provides a population of circulating DNA molecules from a bodily sample (e.g., cfDNA from plasma or peripheral whole blood).
b) converting the population of circulating DNA molecules into a population of nonuniquely tagged parent polynucleotides, wherein each of the non-uniquely tagged parent polynucleotides comprises	Guardant's sequencing platform converts the population of cfDNA into a population of nonuniquely tagged parent polynucleotides.
(i) a sequence from a circulating DNA molecule of the population of circulating DNA molecules, and	Guardant's sequencing platform uses non-uniquely tagged parent polynucleotides having a sequence from a circulating DNA molecule.
(ii) an identifier sequence comprising one or more polynucleotide barcodes,	Guardant's sequencing platform uses an identifier sequence of at least one or more polynucleotide barcodes.
such that each nonuniquely tagged parent polynucleotide is substantially unique with respect to other non-uniquely tagged parent polynucleotides in the population;	Guardant's sequencing platform produces non-uniquely tagged parent polynucleotides that are substantially unique with respect to other non-uniquely tagged parent polynucleotides.
c) amplifying the population of nonuniquely tagged parent polynucleotides to produce a corresponding population of amplified progeny polynucleotides;	Guardant's sequencing platform amplifies the population of non-uniquely tagged parent polynucleotides.
d) sequencing at least a portion of the population of amplified progeny polynucleotides to produce a set of sequence reads;	Guardant's sequencing platform sequences the amplified polynucleotides.
e) grouping the sequence reads into families,	Guardant's sequencing platform groups reads into families.
each of the families comprising sequence reads comprising the same identifier sequence and having the same start and stop positions,	Guardant's sequencing platform groups reads into families using the identifier sequence (*e.g.,* barcode) and having the same start and stop positions.
whereby each of the families comprises sequence reads amplified from the same non-uniquely tagged parent polynucleotide; and	Guardant's sequencing platform produces families of sequence reads amplified from the same non-uniquely tagged parent polynucleotide.
f) collapsing sequence reads in each family	Guardant's sequencing platform collapses sequence reads in each family

to yield a base call for each family corresponding to one or more genetic loci.	corresponding to one or more genetic loci.

As shown in the example above, for most claim limitations, plaintiffs simply parrot claim language. Where plaintiffs do provide additional information, it is cursory and without citation. (See the reference to cfDNA above).

Additionally, plaintiffs miss important limitations altogether. For example, in several limitations, plaintiffs allege that the claimed "sequence reads" are met by what is generically described as "reads." It is unclear whether plaintiffs are making a distinction between "sequence reads" and "reads" in these instances. As another example, in element 1(f), plaintiffs ignore the claim limitation requiring that the method "yield a base call for each family."

These deficiencies occur with respect to most or all claims charted by plaintiffs, across all asserted patents. We therefore ask that plaintiff immediately supplement to separately address each limitation of the asserted claims, and to provide additional narrative information demonstrating how the allegedly accused products and services perform each such limitation.

3. Citations to Documents

Plaintiffs' citations to documents in the claim charts are unhelpful. Nowhere in the body of the charts do plaintiffs pinpoint-cite or quote any of the cited documents to provide notice as to what portion of the document plaintiffs believe supports their assertions of infringement of the claim limitation at issue.

Instead, plaintiffs string-cite documents, often multiple pages of documents, without any narrative explanation or indication as to why they are being cited or what portion of the claim limitation they pertain to.

Plaintiffs' citations would be unhelpful even if the claim limitations were broken down into smaller pieces in plaintiffs' claim charts, but plaintiffs often address limitations containing dozens of words in a single row, rendering string cites to documents even less useful. For example, regarding element 25.c of the '951 Patent, on page 25 of the '951 Patent chart, plaintiffs string cite more than a dozen pages of documents in reference to a limitation that is about 70 words long. No indication is provided about which of those approximately 70 words (or which terms within that set of words) the cited documents pertain to, or which portions of the documents are allegedly relevant.

It is not Guardant's responsibility to hunt through cited documents to piece together what plaintiffs' contentions might be. Rather, plaintiffs have the burden of providing notice of their

infringement theories. Plaintiffs' charts and their non-specific document citations fail to do so.

We therefore ask that plaintiffs include in their supplement pinpoint citations and/or quotations from cited documents do provide notice of their infringement contentions.

4. Grouping and Stacking Accused Products

Plaintiffs group allegedly infringing products in their claim charts. For example, plaintiffs grouped Guardant 360 LDT and Guardant 360 CDx together. Similarly, GuardantOMNI and TissueNext are grouped, as are Guardant Reveal and LUNAR-2. Plaintiffs have failed to provide any basis for these groupings or explain why a contention as to the group is sufficient to allege or prove infringement of each member of the group, except that Guardant may use the same internal name for certain products. While this may be true, Guardant has not admitted or conceded that infringement against one Accused Product will establish infringement against any other. The fact that internal designations may be shared does not excuse plaintiffs from proving infringement for each of the Accused Products.

Plaintiffs have also stacked multiple groups of Accused Products in each chart. All three groups identified above are addressed in a single claim chart. The upshot is that plaintiffs purport to assert infringement of the six grouped products, and the five additional Accused Products, in a single claim chart. As with the groups of accused products, plaintiffs make no attempt to explain why its claims of infringement for one group of products applies to the other groups in the claim chart. Nowhere in any of the charts do plaintiffs adjust their claims of infringement for any specific product or group, except to string cite different documents with no explanation.

Plaintiffs' charts – which purport to include its claims of infringement for 11 distinct and in many cases unrelated products and services – fail to put Guardant on notice of what plaintiffs are alleging with respect to each Accused Product or group of Accused Products (or for the Accused Products collectively, as detailed elsewhere in this letter).

5. Failing to Address Disjunctive Claim Limitations

Plaintiffs' claim charts repeatedly fail to identify which of two claimed features – linked disjunctively with an "or" in the claim – are allegedly practiced by the Accused Products.

For example, claim 1(a) of the '631 Patent claims an adaptor molecule comprising "a degenerate ***or*** semi-degenerate single molecule identifier (SMI) sequence that alone ***or*** in combination with the target nucleic acid fragment ends uniquely labels" target. (emphasis added). Plaintiffs' simply repeats this claim language without indicating whether the SMI sequence is degenerate or semi-degenerate, or whether unique labeling occurs by the SMI sequence alone or in combination with fragment ends, and thus fails to provide notice of plaintiffs' contentions. Plaintiffs must have had some basis to allege infringement of this

limitation; plaintiffs cannot withhold that information and equivocate about how the claim is infringed.

For other illustrative examples of this type of analytical failure, see the portions of plaintiffs' claim charts pertaining to: claim 10 of the '631 Patent (parroting claim language and alleging that "Guardant's sequencing platform includes having a Y-shape adaptor molecule, a U-shape adapter, ***or*** a combination thereof" (emphasis added)); claim 18 of the '631 Patent (parroting claim language and alleging that "Guardant's sequencing platform uses one or more fragment features, which includes a shear point ***or*** other fragment region, ***or*** a combination thereof." (emphasis added)); claim 6 of the '699 Patent (parroting claim language and alleging that "Guardant's sequencing platform selectively enriches regions from a genome ***or*** transcriptome of the subject prior to sequencing" (emphasis added)); claim 11 of the '127 Patent (parroting claim language and alleging that "Guardant's sequencing platform uses double-stranded DNA fragments that have at least one of a delaminated nucleic acid base, and chemically ***or*** enzymatically treats the double-stranded DNA fragments to remove ***or*** repair one or more damaged bases." (emphasis added)); claim 14 of the '127 Patent (parroting claim language and alleging that "Guardant's sequencing platform uses adapters having the barcode in at least one of a double-stranded portion ***or*** a single-stranded portion of the adapter." (emphasis added)); claim 18 of the '127 Patent (parroting claim language and alleging that "Guardant's sequencing platform relates first strand and second strand sequence reads derived from the same particular original adapter-DNA molecule based on a barcode sequence, a fragment-specific feature, ***or*** a combination thereof." (emphasis added)).

6. Asserting 108 claims

Plaintiffs purport to assert 108 claims. That number is excessive and unnecessary, especially in light of the fact that the patents are related and contain claims covering overlapping subject matter.

Plaintiffs' assertion of such an unreasonably large number of claims creates unnecessary burdens and inefficiency in the case, including in the preparation of invalidity contentions due May 3, 2022.

When plaintiffs supplement, we propose that plaintiffs limit the number of asserted claims to 20 overall (5 claims per asserted patent). This is in line with what the Court has approved in other cases. *See*, *e.g.*, *Vaxcel Int'l Co. v. HeathCo LLC*, C.A. No. 20-224-LPS (D. Del. Feb. 3, 2022) (approving a reduction during claim construction to "15 claims across 4 patents"); *IP/DE*, Claim Narrowing in Patent Cases, at https://ipde.com/blog/2021/02/15/how-many-claims-and-references-does-delaware-permit-and-after-markman-some-data/ (finding, based on review of 40 cases, that D. Del. narrows to median of 5 claims per patent pre-*Markman*). That number is also in line with the number of claims asserted by Guardant in this case.

Guardant is open to discussing a stipulation and proposed order setting forth a reasonable schedule for the reduction of asserted claims and invalidity references. However, in light of the impending deadline for invalidity contentions and other case deadlines, plaintiffs must reduce the number of asserted claims now – any such reduction can be built into a negotiated schedule. In other words, if plaintiffs reduce asserted claims to 20 now, Guardant will not insist on a further pre-Markman reduction as part of a negotiated case-narrowing schedule.

* * *

As noted above, we are available to meet and confer on the above issues. Please let us know your availability.

Regards,

/s/ Jeff Castellano

Jeff Castellano

EXHIBIT C

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May 9, 2022
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Re: TwinStrand Biosciences, Inc. et al. v. Guardant Health, Inc., No. 21-cv-1126-VAC-SRF (D. Del.)

Dear Anna:

I write in response to your May 3, 2022 letter regarding Guardant's supplemental responses to Plaintiffs' First Set of Interrogatories, which Guardant has repeatedly represented that it is in the process of supplementing; and Guardant's responses to Plaintiffs' First Set of Requests for Production for Documents (Nos. 1–80).

Guardant has been working diligently to supplement its responses. Given that Plaintiffs have only produced roughly 70 documents to date, including the four asserted TwinStrand Patents and their file histories, Guardant cannot reasonably be expected to provide complete Interrogatory responses at this stage.

I. Discovery requests directed to Accused Services

a. Interrogatory Nos. 4 and 5

As Guardant has repeatedly represented, the Accused Services do not practice any sequencing steps. Neither Plaintiffs' preliminary nor supplemental infringement contentions show how Plaintiffs contend the Accused Services purportedly infringe the TwinStrand Asserted Patents.

As discussed during our May 4, 2022 meet and confer, we will produce additional documents sufficient to show the function of the Accused Services. Once Plaintiffs have either articulated a tenable basis for their infringement allegations as to the Accused Services, Guardant is willing to revisit its responses to Interrogatories Nos. 4 and 5.

b. RFP Nos. 1–4, 6–10, 14–19, 29, 33, 34, 49, and 50 & Sales Figures

As discussed during our May 4, 2022 meet and confer, we will produce additional documents sufficient to show the function of the Accused Services. Once Plaintiffs have either articulated a tenable basis for their infringement allegations as to the Accused Services, Guardant is willing to revisit its

responses and production in response to RFP Nos. 1–4, 6–10, 14–19, 29, 33, 34, 49, as well as sales figures for the Accused Services.

Guardant had produced the available sales data for the Accused Products incompliance with Paragraph 7(b) of the Scheduling Order (D.I. 20). Guardant will update its production of sales data in due course.

II. Supplemental interrogatory responses to Interrogatory Nos. 9–13

a. Interrogatory No. 9

Guardant will supplement its response to Interrogatory No. 9 when it supplements its other responses on May 13, 2022 as previously agreed. Guardant reiterates that, given that Plaintiffs have only produced roughly 70 documents to date, including the four asserted TwinStrand Patents and their file histories, Guardant cannot reasonably be expected to provide complete Interrogatory responses at this stage and Guardant reserves the right to further supplement its responses as discovery progresses.

b. Interrogatories Nos. 10 and 12

Guardant will supplement its responses to Interrogatories Nos. 10 and 12 when it supplements its other responses on May 13, 2022 as previously agreed. Guardant reiterates that, given that Plaintiffs have only produced roughly 70 documents to date, including the four asserted TwinStrand Patents and their file histories, Guardant cannot reasonably be expected to provide complete Interrogatory responses at this stage and Guardant reserves the right to further supplement its responses as discovery progresses.

c. Interrogatory No. 13

Guardant will supplement its response to Interrogatory No. 13 when it supplements its other responses on May 13, 2022 as previously agreed. Guardant reiterates that, given that Plaintiffs have only produced roughly 70 documents to date, including the four asserted TwinStrand Patents and their file histories, Guardant cannot reasonably be expected to provide complete Interrogatory responses at this stage and Guardant reserves the right to further supplement its responses as discovery progresses.

III. "Digital Sequencing Technology": RFP Nos. 2–11, 13–22, 29, 31–34, 39–46, 49, 50, 55–57, 69, 73, and 75

As previously discussed during our past meet and confers, [redacted] nor is it a term of art, and the term

appears to have been used at some point by Guardant's marketing team. We have repeatedly requested that Plaintiffs clarify this term and what is sought in response to requests containing this term, and Plaintiffs have refused to do so. Guardant is not withholding any otherwise relevant documents on this basis.

Best regards,

Monica De Lazzari

MID:

EXHIBIT D

REDACTED IN ITS ENTIRETY

EXHIBIT E

REDACTED IN ITS ENTIRETY

EXHIBIT F

REDACTED IN ITS ENTIRETY

CERTIFICATE OF SERVICE

I, Jeff Castellano, hereby certify that on this 14th day of October, 2022, a copy of **RESPONSIVE LETTER TO THE HONORABLE SHERRY R. FALLON FROM JEFF CASTELLANO REGARDING DISCOVERY DISPUTE** was served upon the following counsel of record via electronic mail:

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/s/ Jeff Castellano
Jeff Castellano (DE Bar No. 4837)